



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-99-18

December 16, 1998

Joseph D. Raposa, President  
Virjo Seafood, Inc.  
601 Roosevelt Boulevard  
Tarpon Springs, Florida 34689

Dear Mr. Raposa:

On October 20 and 21, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 601 Roosevelt Blvd., Tarpon Springs, FL. The investigator documented deviations from the Seafood HACCP Regulation in Title 21, Code of Federal Regulations, Part 123 (21CFR 123), causing the seafood products processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

Failure to have and implement a written HACCP plan for the grouper received and distributed by your firm, to control the potential ciguatera hazard that is reasonably likely to occur. [21 CFR 123.6(b)] We note that your hazard analysis dismissed ciguatera toxin as a hazard because the product was intended to be cooked. Please be aware that this toxin cannot be controlled by heat.

Your HACCP plan for stone crab claws lacks appropriate critical limits, including cooking time by weight, time and temperature of the cooling after cooking, intermediate storage, grading and packing and finished product storage. [21 CFR 123.6(c)(2)]

Failure to maintain records of the monitoring of the cooking critical control point in your HACCP plan for cooked stone crab claws. [21 CFR 123.6(c)(7)] For each critical control you must also develop appropriate critical limits and provide for monitoring, corrective actions, recordkeeping and verification.

Failure to maintain sanitation control records [21 CFR 123.11(c)] that document the monitoring and correction of sanitation conditions specified in the regulations [21 CFR 123.11(b)], for example, plant water (ice) safety, condition and cleanliness of

food contact surfaces, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, protection from contaminants, proper labeling, storage, and use of toxic compounds, control of employee health conditions, and exclusion of pests.

In addition, you failed to have your HACCP plan for cooked stone crab claws signed by the most responsible individual at your company. [21 CFR 123.6(d)]


The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export of any of the seafood products processed at your facility until your firm is fully in compliance with the seafood HACCP regulation.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas D. Tolen". The signature is fluid and cursive, with a large initial "D" and a stylized "T".

Douglas D. Tolen  
Director, Florida District